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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,958

11/28/2006

Pierre Martin

LNK-018

4554

31496

7590

09/24/2009

SMITH PATENT CONSULTING, LLC  
3307 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

09/24/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chalin@smithpatent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/586,958	<b>Applicant(s)</b> MARTIN ET AL.	
	<b>Examiner</b> SUSANNAH CHUNG	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 24-28 and 30-44 is/are pending in the application.
- 4a) Of the above claim(s) 25-28, 32-35, 37-39, 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6, 24, 30 and 42 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 5, 7, 31, 36, 41 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/26/06</u>   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-7, 24-28 and 30-44 are pending in the instant application. Claims 8-23 and 29 are canceled. Claims 30-44 are new.

#### ***Priority***

This application is a 371 of PCT/EP05/00793, filed 01/27/2005, which claims benefit of 60/543,463, filed 02/10/2004.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) by application no. EPO04100303.9 filed in the European Patent Office on 01/28/2004, which papers have been placed of record in the file. The application names an inventor or inventors named in the prior application.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS), filed on 7/26/06 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

#### ***Response to Election/Restrictions***

Applicant's election with traverse of Group I, process of making a compound of formula [A], in the reply filed on 5/12/2009 is acknowledged. The election of the species Rizatriptan is acknowledged for search and examination purposes.

The traversal is on the ground that all of the pending claims, i.e. claims 1-7, 24-28 and 30-44 are linked and there is no search burden to examine the various processes of making and compounds together. Applicants arguments are acknowledged. Examiner respectfully disagrees. The claims have been amended to be dependent on claim 1. Changing the dependency of the claim does not change the

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subject matter of the claim and does not make it the same invention as claim 1 or Group I of the previous restriction requirement.

In addition, Claims 1-7, 24-28 and 30-44 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2. PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept (requirement of unity of invention). PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(b), provides that “special technical features” mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1(e), provides combinations of different categories of claims and states:

“The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

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(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specifically designed for carrying out the said process,..."

The instant claims as amended now contain the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The following groups are exemplary.

- I. Claims 1-7 drawn to a process of making a compound of formula [A].
- II. Claims 24, 30-31, 36, 40-41 and 44 drawn to processes of making and a compound of formula [B].
- III. Claim 25, 32 and 33 drawn to a process of making and a compound of formula [D].
- IV. Claims 26-27, 37 and 38 drawn to a process of making and a compound of formula [C].
- V. Claims 28 and 43 drawn to a process of making and a compound of formula [O].
- VI. Claim 34 drawn to a process of making a compound of formula [E].
- VII. Claim 35 drawn to a process of making a compound of formula [G].
- VIII. Claim 39 drawn to a process of making a compound of formula [N].

The above groups demonstrate the search burden. There are multiple compound and process claims. Each compound claim requires a structure search and the different compounds will have different search parameters posing a search burden if

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all compounds have to be searched together. In addition, each process claim requires a search of the process steps in addition to a structure search posing an additional burden. Also, one prior art may not be used for more than one group, which poses an additional search burden to find additional prior art. Therefore, in accordance with international rules, the compound and process of making the compound will be searched together, but additional compounds and processes cannot be searched together. The restriction requirement mailed on 3/16/2009 has been deemed proper and is maintained.

### ***Scope of the Elected Invention***

Claims 1-7, 24-28 and 30-44 are pending in this application. Claims 24-28 and 30-44 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the elected subject matter that will be examined and searched is as follows: Claims 1-7 in its entirety.

### ***Rejoinder***

Claims 2-3, 5 and 7 are objected to, but are directed to an allowable process. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 24, 30-31, 36, 40-41 and 44, directed to the process of making the intermediate, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully

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examined for patentability under 37 CFR 1.104. Claims 25-28, 32-35, 37-39, and 42-43, directed to the invention(s) of a compound or process of making a compound of formula [C], [D], [E], [G], [N], and [O] do not require all the limitations of an allowable product claim, and HAVE NOT been rejoined.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement groups I and II (directed to a method of making a compound of formula [A] and a compound and method of making a compound of formula [B]) as set forth above and on 3/16/2009 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

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Claims 1 and 5 are not enabled for the term "1,2,4-triazolyl forming reagent" because the instant disclosure does not provide support for all potential forming reagents. The instant disclosure provides support for the following 1,2,4-triazolyl forming reagents only: 1,3,5-triazine, formamidine and formamidinium salts.

Claims 1 and 24 are not enabled for the term "protecting groups." The instant disclosure does not provide support for all protecting groups. It appears from the instant disclosure that R2 is always hydrogen. If there are additional groups, please point them out. The claims should be amended to what is defined in the instant disclosure.

Claim 6 is not enabled for the phrase "and derivatives." The instant disclosure does not provide support for all formamidinium salts and derivatives. It is not clear whether the phrase "and derivatives" is directed to different salt forms or different formamidinium compounds. The instant disclosure provides support for formamidinium salts, but not the derivatives of this compound.

Claims 24, 30 and 42 are not enabled because of the term "residue." The term residue implies that additional moieties may be present, but the instant disclosure only provides support for the stated groups, i.e. hydrocarbon. Deletion of the term residue will obviate this rejection.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.



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Claims 1, 4, 6, 24, 30, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 6, is indefinite because the phrase “reacting with a 1,2,4-triazolyl forming reagent a hydrazine compound of the formula [B]” is unclear and indefinite. The metes and bounds of the claim are not known. Further clarification is required.

Claim 1 and 24 are indefinite because the term “protecting group” is not clear. The metes and bound of the claim are not known. Deletion of this term will obviate this rejection.

Claim 4, line 5, is indefinite because the phrase “into a different salt” is not clear. Claim 4 contains different salts and the different salt is unknown. Further clarification is required.

Claim 6, line 3, is indefinite because of the phrase “and derivatives” is not clear. The metes and bounds of the terms are not known. Deletion of the phrase “and derivatives” will obviate this rejection.

Claims 24, 30 and 42 are indefinite because the term “residue” is not clear. The metes and bounds of the term is not known. Deletion of the term residue will obviate this rejection.

### ***Claim Objections***

Claims 2-3, 5, 7, 31, 36, 40, 41 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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### ***Conclusion***

Claims 1-7, 24, 30-31, 36, 40-41 and 44 have been examined.

Claims 25-28, 32-35, 37-39, and 42-43 are withdrawn.

Claims 1, 4, 6, 24, 30 and 42 are rejected.

Claims 2-3, 5, 7, 31, 36, 41 and 44 are objected.

The closest prior art of record is Dalmases Barjoan (WO/2004/014877), which teaches a similar process of making Riztriptan using a hydrazine, but does not teach the use of the instantly claimed hydrazine of formula [B], wherein an alkyl-amino group is present.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Susannah Chung/  
Examiner, Art Unit 1626